REMARKS

Claims 30-53 have been canceled without prejudice or disclaimer. Claims 54-70 have been added and therefore are pending in the present application. Claims 54-70 are supported by claim 30-53. Claim 55 is further supported by page 6, lines 1-3 of the specification. The sequence of amino acids 32-225 of SEQ ID NO: 2 recited in claims 66 and 68 excludes the signal peptide.

Because Applicants obtained patent protection for the xylanases and feed additives in the parent application no. 09/115,560, which issued as U.S. Patent No. 6,245,546. Applicants have presented only claims on animal feed compositions.

It is respectfully submitted that the present amendment presents no new issues or new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 30-40 under 35 U.S.C. 112

Claims 30-40 are rejected under 35 U.S.C. 112, first paragraph, "because the specification, while enabling for a xylanase from *Thermomyces lanuginosus* (also known as *Humicola lanuginosus*) strain DSM 4109, with amino acid sequence SEQ ID NO: 2, does not reasonably provide enablement for any xylanase enzyme...." This rejection is respectfully traversed.

Under 35 U.S.C. § 112, "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same." This requires an applicant to provide sufficient information so that one of ordinary skill in the art can practice the claimed invention without the necessity for undue experimentation.

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art.... The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed....

In re Wands, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

Applicants respectfully submit that the specification fully enables the practice of Applicants' claimed invention.

The present invention is directed to animal feed compositions comprising a xylanase of Family 11 having specified properties. Applicants have demonstrated these enzymes have improved feed enhancing properties.

On the basis of Applicants' disclosure, one skilled in the art would know where to search for xylanases for use in the present invention. The specification discloses that such xylanases can be obtained from *Byssochlamus*, *Chaetomium*, *Humicola*, *Malbranchea*, *Mucor*, *Myceliophthora*, *Paecilomyces*, *Talaromyces*, *Thermoascus*, *Thermomyces* or *Thielavia* strains.

Methods for screening such strains to find ones which produce xylanases with the specified properties are well known. Indeed, these screening methods are routine for persons skilled in the art. Applicants, therefore, submit that the specification provides sufficient guidance to one skilled in the art to isolate xylanases for use in the present invention.

The facts in the present case are similar to those in *In re Wands*, *supra*. There, the claimed invention involved methods for the immunoassay of hepatitis B surface antigen (HBsAg) by using high-affinity monoclonal IgM antibodies having specified properties. A hybridoma cell line that secretes IgM antibodies against HBsAg was deposited at a recognized cell depository. The claims, which were not limited to the deposited cell line, were rejected for lack of enablement. The Federal Circuit reversed the rejection as follows:

> When Wands' data is interpreted in a reasonable manner, analysis ... leads to the conclusion that undue experimentation would not be required to practice the invention. Wands' disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.
>
> The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that undue experimentation would be defined in terms of the number of hybridomas that were never screened.

In re Wands, 8 U.S.P.Q.2d at 1406-07.

Applicants also respectfully submit that requiring applicants to limit the claims to the xylanase of SEQ ID NO: 2 would be contrary to public policy as set forth in *In re Goffe*, 191 U.S.P.Q. 429, 431 (C.C.P.A. 1976):

> For all practical purposes, the board would limit appellant to claims involving the specific materials disclosed in the examples, so that a competitor seeking to avoid infringing the claims would merely have to follow the disclosure in the subsequently-issued patent to find a substitute. However, to provide effective incentives, claims must adequately protect inventors. To demand that the first to disclose shall limit his claims to what he has found will work or to materials which meet the guidelines specified for 'preferred' materials in a process such as the one herein involved would not serve the constitutional purpose of promoting progress in the useful arts.

In the instant case, claims limited to the specified sequence would not adequately protect the inventors. Based on the teachings of the present application, one skilled in the art would attempt to find another xylanase having the properties recited in the instant claims and thereby attempt to circumvent the literal scope of Applicants' patent rights.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 30-40 under 35 U.S.C. 112

Claims 30-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is respectfully traversed.

It is well settled "[t]he test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter...." *In re Kaslow*, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

Applicants have identified numerous sources for the xylanases used in the present invention, including *Byssochlamus*, *Chaetomium*, *Humicola*, *Malbranchea*, *Mucor*, *Myceliophthora*, *Paecilomyces*, *Talaromyces*, *Thermoascus*, *Thermomyces* and *Thielavia*. Applicants submit that the skilled person, based on the general knowledge available in the art, and the information provided in the specification, is capable of obtaining xylanases used in the present invention.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. The Rejection of Claims 30-53 under 35 U.S.C. 102 and 103

Claims 30-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Lischnig et al. (Biotechnology Letters, Vol. 15, No. 4, pp. 411-414 (1993)) or Gomes et al. (Appl. Microbiol. Biotechnol., Vol. 39, pp. 700-707 (1993)) or, in the alternative, under 35 U.S.C. 103 as obvious over Lischnig et al. or Gomes et al. and Alam et al. (Enzyme Microb. Technol., Vol. 16, pp. 298-302 (1994)). This rejection is respectfully traversed.

Lischnig et al. disclose an endo-beta-xylanase derived from *Thermomyces lanuginosa*, DSM 5026, which has a pH optimum of 6.5 and is active at pH values up to 9.0, and has a residual activity of at least about 80% after incubation at 70°C for 10 minutes at pH 6-9. Lischnig et al. also disclose that the xylanase shows sufficient thermostability for use as a bleaching aid in the pulp and paper industry.

Gomes et al. disclose a xylanase derived from a *Thermomyces lanuginosa* strain, which was deposited at Deutsche Sammlung von Mikroorganismen und Zellkulturen under the number DSM 5826. Gomes et al. further disclose that the xylanase was almost thermostable (91-92%) at pH 6.6 and 9.0 after 41 hours preincubation at 55°C and lost only 20-33% activity after 188 hours. Gomes et al. further disclose that the xylanase is extremely valuable in the bleaching of paper pulp.

However, neither Lischnig et al. nor Gomes et al. disclose the animal feed compositions comprising a thermostable xylanase of Family 11, as claimed herein.

Alam et al. disclose thermostable xylanases derived from *Thermomyces lanuginosus* and *Thermoascus aurantiacus*. Alam et al. further disclose that these thermostable xylanases hold a great potential for application in pulp, paper, and jute fiber processing industries.

Significantly, none of the cited references teach or suggest the use of thermostable xylanases in animal feed compositions or that there would be any advantage to using a thermostable xylanase over a thermolabile xylanase in animal feed.

Moreover, Applicants have demonstrated that the use of thermostable xylanases of Family 11 according to the present invention significantly improves feed utilization as compared to other xylanases. For example, in Example 8, Applicants have compared the digestability of animal feeds comprising a thermostable xylanase of Family 11 ("A" and "B") vs. the digestability of an animal feed comprising Bio-Feed Plus ("C"), a commercially-available xylanase preparation

derived from *Humicola insolens*. The results show that the use of Bio-Feed Plus at a dose of 400 FXU/kg gave a % fat digestion of 72.4, whereas the animal feeds comprising a xylanase of the present invention gave a % fat digestion in the range of 72.1-74.3 even though the xylanase was dosed at 100 or 200 FXU/kg (one quarter or one-half, respectively, of the Bio-Feed Plus). These results demonstrate that animal feeds comprising a thermostable xylanase of Family 11 have a significantly better digestability than an animal feed comprising Bio-Feed Plus. Since the demonstrated superior property is not predicted by the prior art, these results are surprising and unexpected and the showing overcomes any assertion of obviousness based on the cited art.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. The Rejection of Claims 30-53 under the Doctrine of Obviousness-Type Double Patenting

Claims 30-53 are rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 and 7-17 of U.S. Patent No. 6,245,546.

Applicants will submit a terminal disclaimer upon an indication of allowable subject matter.

V. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

Date: November 7, 2002

Elias J. Lambiris, Reg. No. 33,728
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212) 840-0097